

BAA-NIH-NIAID-NCRR-DMID-03-36 Amendment #1 (Questions & Answers)

This Amendment provides questions submitted by potential applicants/offerors and the responses provided by the NIAID. This Amendment will be updated at least weekly to add any further questions and their related responses. **All potential offerors are advised to refer back to this Amendment #1 for additional Q&A.**

“Regional Biocontainment Laboratories (RBL) and National Biocontainment Laboratories (NBL)”

Amendment to Solicitation No.: [BAA-NIH-NIAID-NCRR-DMID-03-36](#)

Amendment No.: 1

Issue Date: November 5, 2002 (Questions 1 – 21)

Proposal Due Date/Time: February 10, 2003, at
4:00 P.M., EST

Issued By: Kristen Mistichelli
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Applicants/Offerors must acknowledge receipt of this Amendment #1 on each copy of the application/proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your application/proposal.

The hour and date specified for receipt of applications/proposals HAS NOT been extended.

The following answers are provided concerning a number of inquiries we have received for the above numbered acquisition:

Question 1 It is my understanding from reading the RFP that the parties that are awarded the contracts will own 100% of the building; however, NIH would control 100% of the activity in the building for 20 years. If a contractor contributes 25% of the cost of the building should the contractor be able to control 25% of the work done in that building?

No. See page 7, item 6 of the BAA. Additionally, the priorities for usage of the facilities are described on page 5, first paragraph of Parts A and B.

Question 2 Will the contractor be allowed to charge a profit on the construction of the building?

No. This solicitation has been issued to eligible non-profit organizations. Please note that any subcontract issued to for-profit construction companies can contain a reasonable fee/profit on the subcontract.

Question 3 Can the contractor stipulate in the proposal that it is contingent upon being awarded the operating contract?

We have significant concerns about building a facility and then having another contractor be awarded the contract to operate a facility on our campus. If we are responsible for security, safety and the overall operations then another company operating a facility we own is an issue.

The BAA is silent regarding an operations contract for the NBL except for pg 6 where it states that the awardee may "compete" for an operations contract. Previous information from NIAID had indicated the intent to award an operations contract simultaneously with the construction contract. Is this still the intent? If not, is it contemplated that the operations contract might be awarded to an institution that did not build the facility? When will the solicitation be released?

NBL awardees will be eligible to submit a separate proposal for support activities related to the operation and maintenance of the NBL.

Question 4 Can the government provide any assurance as to the level of contracts/grants placed in the RBL/NBL over the next 20 years?

No.

Question 5 If the contractor elects to propose on a RBL (grant based) instead of the NBL (contract based) how will it get a return on its investment through the grants?

See Question #2, above.

Question 6 Will the arrangement be that the contractor leases the building to NIH?

No.

Question 7 Will the contractor be able to depreciate the building and include that in their indirect rates?

The contractor should follow good accounting practices in accordance with that organization's approved accounting procedures and applicable laws and regulations.

Question 8 Will the contractor be able to charge per diems for animals in the facility?

Yes. See page 6, paragraph 1, of the BAA.

Question 9 We have significant concerns about the impact on insurance rates from the standpoint of increased risk related to doing BSL-4 work and also the possibility of conducting human clinical trials. If the contractor is unable to get reasonable insurance, is NIH willing to provide it? If the contractor is able to get insurance but at a much higher rate, can the premium associated to the new facility be charged to the projects conducted in that facility?

Insurance for the operation of the facility is outside of the scope of this announcement. The core costs of operating the facility will be included in a separate Operation and Maintenance contract. Insurance may be included as one of the core costs.

Question 10 How many principal investigators should such a facility support? I understood from the August briefing that I attended that up to 20 PIs could, in principal, utilize this facility at any one time. However, I understood that the construction grant does not allow for extensive contiguous conventional laboratory or office space. Is this true?

The Notice of Intent (NOT-AI-02-038) dated July 19, 2002 and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. Personnel support for the operation of the facility is outside of the scope of this announcement. Minimum square footage for the NBLs is indicated on page 10 of the BAA. The size and capacity of the RBLs is not specified and is dependent upon the proposed usage. Contiguous conventional laboratory and office space are not excluded from the SOW, but should be kept to a minimum to support the BSL-3 and BSL-4 laboratories.

Question 11 What would be the anticipated scale of any clinical isolation capability? Again, from the briefing, I understood that this space should support 5 to 10 people, either for index case observation or in the event of accidental exposure within the rest of the RBL. Would one be able to justify considerably more clinical isolation space (10x)?

The Notice of Intent (NOT-AI-02-038) dated July 19, 2002, and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. Clinical facilities are not required for the RBLs. For the NBLs, clinical space is required that will support small-scale clinical trials, and a patient containment ward for accidentally exposed users. See page 10 of the BAA for square footage requirements. The NBLs should not include clinical space that would only be used in the event of a bioterrorism emergency.

Question 12 Can you comment on the current anticipated funding level for these projects and the timeline? Does this still reflect the thinking as presented in August? Is it still likely that NIH will sponsor the RBL contracts versus a Department of Homeland Security?

The August presentation was based on the information available at the time of the meeting. The requirements and timeline have evolved. The BAA should be consulted for current guidelines. The Legislation for the creation of the Department of Homeland Security has not been finalized.

Question 13 How does this solicitation change previously issued information in the Notice of Intent and at the August 8th meeting? I am specifically interested in the number of NBL awards (previously announced 5-7) and the budget (up to \$100 million in construction). Is there any guidance regarding the number of RBLs vs NBLs?

The Notice of Intent (NOT-AI-02-038) dated July 19, 2002, and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. The BAA indicates "One (1) or two (2)" potential NBL awards, and four (4) to six (6) RBLs in FY '03 and four (4) to six (6) RBLs in Fy'04. See page 5, paragraph 6, of the BAA anticipated funds available.

Question 14 The BAA refers to a cost share of 25% for the awardee (pg 7, para. 2). Does this provision apply to the construction cost of the NBL? The operation of the NBL?

Yes, for construction costs. The details of the separate operations and management contract have not been determined and are not within the scope of this BAA.

Question 15 Should there be escalation of construction costs, justified claims, force majeure, etc., during the construction phase; what is NIAID's commitment to cover these costs that are above the original project estimate?

It is anticipated that the prime contractor will negotiate a construction contract that is legally sound and that limits the liability of the purchaser. Please review the FAR Clauses contained in the solicitation for General Clauses that are required to be in subcontracts issued under the prime. These FAR clauses include provisions for Claims and Acts of God or nature. NIAID will commit to a maximum amount authorized for construction subcontracts. Therefore, a "Guaranteed Maximum Price" may be negotiated between the prime and subcontractors. Changes to the maximum amount authorized for a subcontract must be negotiated in advance. The following clauses will more than likely be included in any resultant contract:

FAR 52.236-1 Performance of Work by the Contractor

FAR 52.236-2 Differing Site Conditions

FAR 52.236-4 Physical Data

FAR 52.236-5 Material and Workmanship

FAR 52.236-7 Permits and Responsibilities

FAR 52.236-8 Other Contracts

FAR 52.236-10 Operation and Storage Areas

FAR 52.236-11 Use and Possession Prior to Completion

FAR 52.236-12 Cleaning Up

FAR 52.236-13 Accident Prevention

FAR 52.236-15 Schedules for Construction Contracts

FAR 52.236-18 Work Oversight in Cost-Reimbursement Construction Contracts

FAR 52.236-21 Specifications and Drawings for Construction

FAR 52.236-27 Site Visit

FAR 52.246-12 Inspection of Construction

Question 16 The BAA states that "The facility must be utilized for biomedical research projects as determined by NIAID program needs" (pg. 7, para. 6). Our Institution has biodefense contracts from several Federal agencies. Can this work or similar work be performed in the NBL? Or only work funded/approved by NIAID? What specific restrictions on the use of the facility are contemplated?

The facility must give priority to Regional Centers of Excellent for Biodefense and Emerging Infectious Diseases (RCEs), followed by other NIAID funded biodefense research, and finally to biodefense work funded by other agencies and entities. See page 5, paragraphs 2 and 3 of the BAA.

Question 17 Will the Federal Government provide liability insurance, indemnification or other relief regarding the operation of an NBL4?

See question #9, above, regarding insurance for the operation of the facility. Indemnification requires a review and approval process specific to individually awarded contracts. After award of an operating contract, as applicable, the review process can be requested, considered and initiated.

Question 18 Intergovernmental Review, page 11, paragraph 2. Can we assume that only the SPOC of the State where the NBL is sited need be advised and not the states "served by" the NBL?

Yes.

Question 19 In the event that the contract is cancelled by the government prior to completion of construction, what provisions will there be for recovery of cost share and site restoration?

Cost recovery in the event of contract termination will occur in accordance with applicable contract termination clauses and the Federal Acquisition Regulation (FAR).

Question 20 Is this now being conducted as a Grant opportunity? I saw on the NIAID Biodefense site that a BAA has been opened. How does that relate to and impact this requirement?

The BAA includes both NBLs and RBLs. We anticipate that the NBLs will be awarded as contracts, and the RBLs as grants. This solicitation package clearly identifies the portions of this package applicable to the submission of a grant application vs. a contract proposal.

Question 21 What is the status of the Architectural programming and design of NIAID laboratories and centers? Is there a new website? Will additional comment solicitations (such as at Marriott Gaithersburg in August) be occurring.

Our ongoing website is still available but there are no plans for a new website or for additional meetings.